

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-27 (canceled)

Claim 28 (currently amended): A method for inactivating viruses in a ~~body fluid~~ ~~blood or blood component~~, the method comprising the steps of:

initially storing an amount of methylene blue and an amount of the ~~body fluid~~ ~~blood or blood component~~ in separate sterile, sealed containers, each container having an inner surface made of a non-polyvinyl chloride, plastic material and the container in which the ~~body fluid~~ ~~blood or blood component~~ is stored includes portions that are made of a polyvinyl chloride material;

forming a mixture by adding at least a portion of the amount of the methylene blue to the amount of the ~~body fluid~~ ~~blood or blood component~~ wherein the portion of methylene blue is a virucidally effective amount of the methylene blue and further wherein the mixture formed is within one of the containers in which the methylene blue or ~~body fluid~~ ~~blood or blood component~~ is initially stored under sterile conditions; and

irradiating the mixture with a light field of a suitable intensity and wavelength for activating the methylene blue for a time sufficient to inactivate viruses in the mixture, while maintaining the mixture under a substantially no flow condition within the container in which the mixture is formed.

Claim 29 (canceled)

Claim 30 (currently amended): The method of Claim 29~~8~~ wherein the blood component is selected from the group consisting of: plasma, red blood cells, white blood cells, and platelets.

Claim 31 (canceled)

Claim 32 (currently amended): The method of Claim 28 further comprising the step of: adding the methylene blue to the container in which the ~~body fluid~~ blood or blood component is already stored.

Claim 33 (canceled)

Claim 34 (currently amended): The method of Claim 28 further comprising the step of: adding the ~~body fluid~~ blood or blood component to the container that contains methylene blue.

Claim 35 (canceled)

Claim 36 (previously added): The method of claim 28 further comprising the step of: transporting the mixture in the container in which the mixture is formed on a conveyor past at least two light sources.

Claim 37 (canceled)

Claim 38 (previously added): The method of claim 28 wherein the light field is generated by at least one array of light emitting diodes.

Claim 39 (previously added): The method of claim 28 wherein the mixture is irradiated by the light field for a cumulative period of at least five minutes.

Claim 40 (currently amended): A method for inactivating viruses in a ~~body fluid~~ blood or blood component, the method comprising the steps of:

initially storing an amount of methylene blue in a container that includes an interior and at least one port extending from the container that provides controlled access to the interior, the

container is constructed of a plastic material and includes an inner surface made of a non-polyvinyl chloride, plastic material;

forming a mixture by adding at least a portion of the amount of the methylene blue to an amount of the ~~body fluid~~blood or blood component, by use of the port, wherein the portion of methylene blue is a virucidally effective amount of the methylene blue and further wherein the mixture formed is within either the container or in a second container that initially housed the ~~body fluid~~blood or blood component; and

irradiating the mixture with a light field of a suitable intensity and wavelength for activating the methylene blue for a time sufficient to inactivate viruses in the mixture, while maintaining the mixture under a substantially no flow condition within the container in which the mixture is formed.

Claim 41 (canceled)

Claim 42 (currently amended): The method of Claim 41 wherein the blood component is selected from the group consisting of: plasma, red blood cells, white blood cells, and platelets.

Claim 43 (previously added): The method of Claim 40 wherein the container in which the mixture is formed does not include any polyvinyl chloride plastic.

Claim 44 (currently amended): The method of Claim 40 further comprising the step of: adding the methylene blue to the second container in which the ~~body fluid~~blood or blood component is housed.

Claim 45 (previously added): The method of Claim 40 wherein the container in which the mixture is formed includes a polyvinyl chloride material.

Claim 46 (currently amended): The method of Claim 40 further comprising the step of: adding the ~~body fluid~~ blood or blood component to the container that contains methylene blue.

Claim 47 (previously added): The method of Claim 40 wherein the container in which the mixture is formed comprises at least an inner surface made of a non-polyvinyl chloride material.

Claim 48 (previously added): The method of Claim 40 further comprising the step of: transporting the mixture in the container in which the mixture is formed on a conveyor past at least two light sources.

Claim 49 (currently amended): The method of Claim 40 further comprising the step of: allowing excess methylene blue to leach into the container in which the ~~body fluid~~ blood or blood component is stored after mixture with the methylene blue.

Claim 50 (previously added): The method of Claim 40 wherein the light field is generated by at least one array of light emitting diodes.

Claim 51 (previously added): The method of Claim 40 wherein the mixture is irradiated by the light field for a cumulative period of at least five minutes.

REMARKS

In the Office Action, claim 28-30, 32, 34, 38-47, 49 and 51 are rejected under the judicially created doctrine of obviousness-type double patenting; claims 28-30, 32, 34, 36 and 38-51 are rejected under 35 U.S.C. §112, second paragraph; claims 28-30, 32, 34, 36, 38 and 39 are rejected under 35 U.S.C. §112, first paragraph; and claims 40-42, 44, 45 and 49 are rejected under §102. Claims 28, 30, 32, 34, 40, 42, 44, 46 and 49 have been amended; claims 29 and 41 have been cancelled without prejudice or disclaimer; and claims 1-27, 31, 33, 35 and 37 remain cancelled without prejudice or disclaimer from before. Applicants believe that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

At the outset, claims 28-30, 32, 34, 38-47, 49 and 51 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,207,107. In response, Applicants are concurrently filing herewith a Terminal Disclaimer along with the requisite fee. Therefore, Applicants believe that this rejection should be withdrawn.

In the Office Action, claims 28-30, 32, 34, 36 and 38-51 have been rejected under 35 U.S.C. §112, second paragraph. The Patent Office alleges that the claim term “body fluid” is indefinite in meaning. Although Applicants believe that this rejection is improper, in the spirit of cooperation and in an effort to expedite allowance, Applicants have amended the claims to replace the term “body fluid” with the term “blood or blood component.” Claims 29 and 41 have also been cancelled in view of same. Applicants note for the record that this amendment including the cancellation of claims 29 and 41 was made for clarification purposes and further that Applicants do not intend to narrow and/or disclaim the scope of claimed subject matter in view of same.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 28-30, 32, 34, 36 and 39 have been rejected under 35 U.S.C. §112, first paragraph. The Patent Office alleges that the claim term “sealed” is new matter. Although Applicants believe that this rejection is improper, in the spirit of cooperation and in an effort to expedite allowance, Applicants amended claim 28 to delete the term “sealed.” The remaining claims at issue depend from claim 28. Applicants note for the record that this

amendment was made for clarification purposes and further that Applicants do not intend to narrow and/or disclaim the scope of claimed subject matter in view of same. Indeed, the Patent Office even suggests that the term “sealed” is redundant in meaning as applied to the claimed subject matter at issue.

Accordingly, Applicants respectfully submit that this rejection be withdrawn.

In view of the Terminal Disclaimer and amendments in response to the rejections under §112, first and second paragraphs, Applicants believe the record should reflect that pending claims 28, 30, 32, 34, 36, 38 and 39 are allowable claimed subject matter. In this regard, no further rejections and/or objections are asserted against these pending claims.

With respect to claims 40-42, 44, 45 and 49, the Patent Office alleges that these claims are anticipated by U.S. Patent No. 5,445,629 (“*Debrauwere*”). The Patent Office essentially asserts that *Debrauwere* discloses each and every feature of the claimed invention as defined by claims 40-42, 44, 45 and 49. Applicants believe that this rejection is improper.

Of the pending claims at issue, claim 40 is the sole independent claim. Claim 40 relates to a method for inactivating viruses in a body fluid. The method includes the steps of initially storing an amount of methylene blue in a container that includes an interior and at least one port extending from the container that provides controlled access to the interior wherein the container is constructed of a plastic material and includes an inner surface made of a non-polyvinyl chloride, plastic material; forming a mixture by adding at least a portion of the amount of the methylene blue to an amount of the blood or blood component, by use of the port, wherein the portion of methylene blue is a virucidally effective amount of the methylene blue and further wherein the mixture formed is within either the container or in a second container that initially housed the blood or blood component; and irradiating the mixture with a light field of a suitable intensity and wavelength for activating the methylene blue for a time sufficient to inactivate viruses in the mixture, while maintaining the mixture under a substantially no flow condition within the container in which the mixture is formed.

In contrast, Applicants believe that the *Debrauwere* is clearly deficient with respect the claimed invention. For example, nowhere does this reference disclose or arguably suggest initially storing methylene blue in a container, let alone one that is constructed of plastic with an inner surface made of a non-polyvinyl chloride, plastic material as required by the claimed

invention. Indeed, the focus of *Debrauwere* relates to storing blood in a container that has extending therefrom an elongated tube. The elongated tube includes a fluid that can be added to the blood in the container. See, *Debrauwere*, col. 3, lines 52-55.

Once the fluid is added to the blood, the blood can be expressed into the tube which can then be severed from the container for cross matching purposes, for example. See, *Debrauwere*, col. 5, lines 26-35. Thus, nowhere does *Debrauwere* further disclose or arguably suggest forming a mixture of methylene blue and blood or blood component in either the container that stores the methylene blue or the container that stores the blood or blood component wherein the blood or blood component or methylene blue are mixed by use of a port extending from the methylene blue container that provides controlled access to the interior thereof.

Based on at least these reasons, Applicants believe that one skilled in the art would consider that the claimed invention is distinguishable from *Debrauwere*. Therefore, Applicants respectfully submit that *Debrauwere* fails to anticipate and arguably render obvious the claimed invention.

Accordingly, Applicants respectfully request that the anticipation rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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